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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/705,614

11/10/2003

James F. Hainfeld

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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

09/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary

Application No.

10/705,614

Applicant(s)

HAINFELD ET AL.

Examiner

Christine D. Hopkins

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25 and 44-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17, 19-22, 25, 44-57, 60, 62, 63 and 65 is/are rejected.
- 7) ☒ Claim(s) 15, 16, 18, 23, 58, 59, 61, 64 and 66-68 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>19 Dec 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 25 June 2007. Claims 1-23, 25, and 44-68 are now pending. The Examiner acknowledges the amendments to claims 1-2, 11-13 and 25, as well as the cancellation of claims 24 and 26-43, and the addition of claims 44-68.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 44-57, 60, 62-63 and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Esenaliev (U.S. Patent No. 6,165,440). Esenaliev discloses the use of nanoparticles with various forms of radiation for enhancing drug delivery in tumors. Regarding claims 44-47 and 65, Esenaliev teaches a method of enhancing the effects of radiation consisting of the administration of nanoparticles intravenously, and subsequent irradiation of the tumor (col. 2, lines 48-52). The tumor being irradiated may be that of brain, lung or breast tissue (col. 5, lines 50-53), in accordance with claims 48-

Art Unit: 3735

50. Referring to claims 51 and 52, such particles injected intravenously may comprise gold (col. 10, lines 14-18).

Regarding claims 54-57, 60 and 62-63, since the nanoparticles may have a surface layer of material such as an antibody coating, the metal portion of the nanoparticle is being interpreted as the "metal core." Thus, Esenaliev discloses a metal core in the range of 0.1 nm to about 7000 nm (col. 2, lines 20-28).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-14, 17, 19-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esenaliev (U.S. Patent No. 6,165,440). Esenaliev discloses the use of nanoparticles with various forms of radiation for enhancing drug delivery in tumors. Regarding claims 1-4 and 22, Esenaliev teaches a method of enhancing the effects of radiation via the administration of an anti-cancer drug to a tumor, injection of nanoparticles intravenously, and subsequent irradiation of the tumor (col. 5, lines 41-46). The tumor being irradiated may be that of brain, lung or breast tissue (col. 5, lines 50-53), in accordance with claims 5-7. Referring to claims 8-10, such particles injected intravenously may comprise gold (col. 10, lines 14-18).

Regarding claims 11-14, 17 and 19-21, since the nanoparticles have a surface layer of material such as an antibody coating, the metal portion of the nanoparticle is being interpreted as the "metal core." Thus, Esenaliev discloses a metal core in the range of 0.1 nm to about 7000 nm (col. 2, lines 20-28).

However, Esenaliev does not expressly disclose that the radiation is in a form selected from the group consisting of: x-rays, microbeam arrays of x-rays, radioisotopes, electrons, protons, ion beams or neutrons in accordance with claim. Instead, Esenaliev indicates that the form of radiation is microwave, optical or RF, for example (col. 3, lines 66-67 through col. 4, lines 1-3).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to incorporate the radiation taught by Esenaliev in the form of x-rays, microbeam arrays of x-rays, radioisotopes, electrons, protons, ion beams or neutrons because Applicant has not disclosed that x-rays, microbeam arrays of x-rays, radioisotopes, electrons, protons, ion beams or neutrons provides an advantage, is used for a particular purpose, or solves a state problem. It would have been further obvious to administer x-rays at a dose of about 1 KeV to about 25,000 KeV, in accordance with claim 25, because Applicant has not provided any criticality for this particular range, nor that it provides an advantage, is used for a particular purpose, or solves a state problem. One of ordinary skill in the art, furthermore, would have expected Esenaliev's radiation and applicant's invention, to perform equally well with either the radiation as taught by Esenaliev or the claimed

Art Unit: 3735

radiation of claim 1 because the radiation of both inventions would perform the same function of enhancing the effects of radiation and ablating a tissue or population of cells.

Therefore, it would have been prima facie obvious to modify Esenaliev to obtain the invention as specified in claims 1 and 25 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Esenaliev.

Allowable Subject Matter

6. Claims 15-16, 18, 23, 58-59, 61, 64, and 66-68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding claims 15-16 and 58-59, the prior art of record does not teach or fairly suggest a surface layer comprising a molecule comprising a sulfur, phosphorus or amine group, wherein the molecule is thioglucose. Regarding claims 18, 61 and 64, the prior art of record does not teach or fairly suggest that the nanoparticles are polyanions of metals complexed with quaternary ammonium salts for use in radiation. Regarding claims 23 and 66-68, the prior art of record does not teach or fairly suggest the metal nanoparticles are administered to an animal in an amount to achieve a concentration in the tissue of at least about 0.1% by weight.

Response to Arguments

7. Applicant's arguments filed 25 June 2007 with respect to the benefit of a prior-filed application have been fully considered and are acknowledged.
8. Applicant's arguments filed 25 June 2007 with respect to the IDS filed 19 December 2003 have been fully acknowledged and the references considered.
9. Applicant's arguments filed 25 June 2007 with respect to the rejection of claims 11-13 and 25 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 11-13 and 25 has been withdrawn.
10. Applicant's arguments filed 25 June 2007 with respect to the rejection of claims 1-14, 17, 19-22 and 24 under 35 U.S.C. 102(e) citing Esenaliev ('440) have been fully considered but are moot in view of the new grounds of rejection under 35 U.S.C. 103(a) citing Esenaliev ('440) as a design consideration; see rejection *supra*.
11. Applicant's arguments filed 25 June 2007 with respect to new claims 44-68 citing Esenaliev ('440) have been fully considered and the rejection presented above under 35 U.S.C. 102(e).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

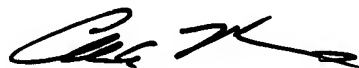
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 3735

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Christine D Hopkins
Examiner
Art Unit 3735



Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735